REMARKS

Claims 1-13 are pending in this patent application. By the amendment, claim 1 has been amended. Reconsideration of this patent application, as amended, is respectfully requested.

Amendment to Specification

Paragraph [0018] of the specification identified in the published patent application (see Pat. App. Pub. No. 2006/0155291) has been amended to refer to a structural feature clearly shown in FIG. 2 of Applicants' originally filed patent application.

35 U.S.C. § 112 Rejection and Associated Comments Regarding the Drawings

Claims 1-13 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner stated in the Office Action that '[t]he claims have been amended to require the invention to further include a surgical tool for cutting, which is not supported by the disclosure as originally filed.

35 U.S.C. § 112, first paragraph, reads as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In the previous amendment filed on May 20, 2009, Applicants amended claim 1 to add the following element:

> a surgical tool having a bone contacting cutting structure positioned in

engagement with the tool engagement guide surface of the guide part during use of the surgical tool.

Applicants' specification as originally filed contains the following paragraphs (see Pat. App. Pub. No. 2006/0155291) (Bolding and italics added for emphasis):

[0026] The guide part 6 of the fixation block has a slot 10 in it. The slot extends through the guide part so that ***a blade inserted into the slot can extend through it and be used to cut a bone*** to which the guide block is fixed. The slot will be dimensioned so that the blade is a sliding fit, as in existing cutting blocks.

[0020] The guide block of the invention finds particular in orthopaedic surgery where accurate positioning of instruments used in surgery, and of prosthesis components, is vitally important. For example, ***the guide block of the invention can be used to locate a saw relative to anatomical features***, especially on a bone, for a resection step. For example, it can be used to locate the plane for the resection of the tibia in the implantation of a knee joint prosthesis. In this procedure, ***a guide block will have a surface against which a saw blade can be positioned***, especially a pair of surfaces which define a slot. The guide block is fastened to the tibia in approximately the correct location relative to previously identified anatomical landmarks, for example by three bone screws which pass through fixation holes in the fixation part of the block. The guide block will include three drives by which the location of the guide part can be adjusted relative to the fixation part. A first drive can adjust the anterior-posterior tilt of the guide part. The second drive can adjust the medial-lateral tilt of the guide part. The third drive can adjust the spacing between the guide and fixation parts along a desired axis, for example essentially along the patient's anatomical axis.

[0009] ***The structural feature can comprise an opening in which a drill bit can be inserted. The guide part of the block can provide more than one opening for a drill bit, for example two or three openings.*** The guide block of the invention can be used in this way to locate accurately a position for an implant, or for another surgical tool which is to be fastened to a patient's bone or other tissue, for example by means of screws.

[0008] In the guide block of the invention, ***the structural feature can comprise a guide surface which can be engaged by a cutting tool such as a blade*** to define the appropriate alignment for a cut. When the guide surface is planar, it will define a cutting plane. However, it can be curved or otherwise non-planar, so that the patient's tissue is cut along a curved line. It might also have two parts which define separate cut lines, which might but need not intersect. The structural feature can comprise a pair of closely spaced guide surfaces which define between them a slot in which a blade can be inserted.

Claim 6. A guide block as claimed in claim 1, in which ***the structural feature comprises a guide surface which can be engaged by a blade*** to define the appropriate alignment for a cut.

Claim 7. A guide block as claimed in claim 1, in which ***the structural feature comprises an opening in which a drill bit can be inserted.***

Based on the above disclosure, one skilled in the art would clearly be able make and use the invention of amended claim 1 which includes " a surgical tool having a bone contacting cutting structure positioned in engagement with the tool engagement guide surface of the guide part during use of the surgical tool." Accordingly, claim 1, as

amended, clearly comports with 35 U.S.C. § 112, first paragraph. For the same reasons set forth above, the drawings are believed to be acceptable.

35 U.S.C. § 102 Rejection

Claims 1 and 3-9 were rejected under 35 U.S.C. § 102 as being anticipated by Hauri (WIPO Publication WO 00/00093). Claim 1 has been amended to more clearly define the invention. Applicants respectfully request reconsideration of claims 1 and 3-9, as amended.

Amendment to Claim 1

Claim 1 has been amended to clarify that the at least one position indicator is *supported by* the guide part. Having the at least one position indicator supported by the guide part contributes significantly to the accuracy in which the guide part may be located. Indeed, prior art systems such as disclosed in Hauri do not provide a position indicator on the guide part itself, but rather its position indicator is located several components upstream in the system which injects the likelihood of error into any position determination being made by such a system. It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Hauri does not disclose each and every element of Applicants' amended claim 1, Hauri does not anticipate Applicants' amended claim 1.

Further Discussion

Hauri discloses an instrument system for preparing a knee for implantation of femoral and tibial components. The system includes a reference device 5 which can be attached, directly or indirectly, to the femur. It has a guide opening 5z in which a toothed rod 10a can slide, aligned with the superior-inferior axis. The rod can be driven along the S-I axis by means of a knurled screw 5v. A base bar 10g is attached to the toothed rod, and the knurled screw 5v provides X-axis adjustment of the bar. The bar can be adjusted along the anterior-posterior axis by means of a second knurled screw 10f which acts on a second toothed rod 10c. Different instruments can be mounted on the base bar. Fig. 11 shows a measuring stylus 101 attached to the base bar, while Fig. 12 shows a saw guide.

Fig. 14 provides brief details of how the system can be controlled by means of a computer. This is achieved by attaching a disc 17c to the shaft 17c of a drive motor, with sensors 17f to measure the angle through which the disc and shaft turn. The drive motor is connected to the knurled screws by means of a flexible shaft 17a. In this way, the extent of any movement of the knurled screws can be monitored by measuring the angular displacement disc on the drive shaft 17c using the sensors. The computer can be used to record positions of the base bar (as when measuring the shape of the bone) or to generate drive signals which move the base bar to a desired position (as when positioning an instrument used in a cutting step.)

When the measuring stylus is attached to the base bar, the base bar can be moved so that the stylus contacts the surface of the bone. A scan of the bone surface can be generated by recording the positions to which the base bar and the stylus are moved. This scan can then be used subsequently to position the base bar when it is fitted with a

saw guide.

The invention of amended claim 1 makes use of a position indicator which is supported by the guide part itself. This is in contrast to the Hauri system in which the position indicator is provided on the drive shaft of a remote drive motor. In both systems, it is necessary for a control computer to be provided with the coordinates of a desired position for the guide part. Hauri provides details of a data gathering step (using the stylus) which can be used when planning the procedure defining that desired position.

In contrast to the invention of amended claim 1, Hauri is concerned with a technique in which its guide part is moved to a desired position which is programmed into the control computer which then generates appropriate signals to move the guide block from its current position to the desired position. Achieving the movement to that position requires that the difference between the current position and the desired position is known accurately. It also requires that the movement from that position to the desired position is sufficiently controlled through the drive imparted by the drive motor, through the flexible shaft.

The invention of amended claim 1 enables greater accuracy by virtue of the position indicator being supported by the guide part itself. This enables the actual position of the guide part to be monitored at all times, allowing the actual position of the guide part to be fine tuned so that the difference between the actual position and the ultimate desired position be minimized towards zero. This helps minimize inaccuracy.

It is clear that the disc 17c is not a position indicator which is supported by and fixed in relation to the base bar (or anything else that is fixedly attached to the base bar); the base bar and the disc having various components interposed such as shaft 17a which

is described as being flexible.

Hauri clearly does not contemplate providing a position sensor which is supported by the sawing jig 11 shown in Fig. 12. It is important for the operation of his system that the sensing components are provided upstream of the drives (rather than downstream on the driven object). This is because the sensing components are used with different components on the base bar, and in both the data collection phase of a procedure, and the subsequent implementation of the procedure.

Hauri therefore omits significant features which contribute significantly to the accuracy with which a cutting guide can be located. The Hauri document teaches a device which requires that sensor components (the disc and the sensor for the disc) are located away from the system component whose position is ultimately to be controlled. This requirement flows directly from the use of the sensor components in a system to monitor the position of a number of different components, connected at different times to the base bar. It is also consistent with the teachings of the Hauri document to place control components in the non-sterile area of an operating theater so as to minimize cleaning requirements.

Hauri discloses another embodiment in Fig. 13 in which a saw is fastened to the base bar by means of an articulating arm. The position of the sawing plane can be adjusted where the articulating arm is mechanically coupled to the base bar; this coupling can be controlled by means of another knurled screw. In this embodiment, sensors can be provided in the joints of the articulating arm to provide position information for the saw blade. The saw is powered through a cable 14b. However, it appears that the position of the saw, as with the sawing jig 11 in Fig. 12, is not monitored directly; all of the position

information for the saw is generated upstream of the saw itself, with the possibility of error due to linkages between the instrument and the component where the position data is generated.

Thus, Hauri teaches away from the idea of providing a position indicator that is supported by the guide part of a guide block. Rather, it only teaches providing position indicators on components to which surgical instruments are mechanically coupled where those couplings are flexible. This is a requirement of the Hauri system where sensors are associated with drive motors which are required to have flexibility to be able to drive a plurality of different components, which are mechanically coupled in turn to the drive motors. The invention of amended claim 1 takes a vastly different approach which allows simplification of the construction of the guide block and, importantly, improved accuracy.

Discussion re: Patentability of Claims 3-9

Each of claims 3-9 depends directly or indirectly from amended claim 1. As a result, each of claims 3-9 is allowable for, at least, the reasons hereinbefore discussed with regard to amended claim 1.

35 U.S.C. § 103 Rejection

Claims 1, 2, 4-6, and 8, and 10-13 were rejected under 35 U.S.C. § 103 as being unpatentable over DeOrio (U.S. Patent No. 5,681,316) in view of Hauri (WIPO Publication WO 00/00093). As stated above, claim 1 has been amended to more clearly define the invention. Applicants respectfully request reconsideration of claims 1, 2, 4-6,

and 8, and 10-13, as amended.

Discussion Regarding Patentability of Amended Claim 1

Amended claim 1 recites the following limitations:

d. at least one position indicator which is supported by and fixed relative to the guide part.

As discussed in detail above, Hauri does not disclose a system in which "at least one position indicator which is supported by and fixed relative to the guide part." Significantly, Hauri's position indicator is located several components upstream in the system which injects the likelihood of error into any position determination being made by such a system. Furthermore, DeOrio does not teach a system in which "at least one position indicator which is supported by and fixed relative to the guide part." Indeed, the Office Action does not even contain such an allegation, but merely states that "DeOrio fails to disclose the device further comprising a computer assistance mechanism and a cutting tool." Thus, even if it would have been obvious to combine Hauri and DeOrio as proposed in the Office Action, the resulting combination would not arrive at a system that possesses "at least one position indicator which is supported by and fixed relative to the guide part." Thus, the proposed combination of Hauri and DeOrio does not arrive at the invention of amended claim 1. Accordingly, the proposed combination of Hauri and DeOrio would not establish a prima facie case of obviousness under 35 U.S.C. § 103 with regard to the invention of amended claim 1.

Discussion re: Patentability of Claims 2, 4-6, 8, and 10-13

Each of claims 2, 4-6, 8, and 10-13 depends directly or indirectly from amended claim 1. As a result, each of claims 2, 4-6, 8, and 10-13 is allowable for, at least, the reasons hereinbefore discussed with regard to amended claim 1.

Conclusion

In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited. It is respectfully submitted that, if necessary for a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response, and any deficiency in fees be charged, or any overpayment in fees be credited, to our Deposit Account No. 13-0014.

Respectfully submitted,

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